APR 1 0 2001

K003731

III. **510(k) SUMMARY**
(As required by 21 C.F.R. 807.92)

A. Submitter Information

Submitter's Name:	Thomas Medical Products, Inc.
Address:	65 Great Valley Parkway Malvern, PA 19355
Telephone Number:	(610) 296-3000
Facsimile:	(610) 296-4591
Contact Person:	Peter J. Rapp
Title:	Director, Quality Assurance/Regulatory Affairs
Date Submission Prepared:	November 30, 2000

B. Device Information

Trade name:	SafeSheath MSP™ Introducer Kit with Integral Hemostasis Valve
Classification Names:	Catheter Introducer
Predicate Devices:	Tearaway Sheath Introducer Set with Integral Hemostatis Valve (K934901)
Device Description:	The components of the SafeSheath MSP™ Introducer Kit consists of a sheath with sideport tubing, stopcock and heomostasis valve. The distal end of the sheath may be configured for a straight sheath or with a curve. The sheath length must be able to provide a conduit from the insertion site to the epicardial target sites. A guiding dilator will accompany the straight or curved sheath, to assist with the guiding and steering of the sheath to the intended location. A standard vessel dilator that will assist in insertion. A .035" x 135 cm guidewire. A standard 12cc syringe. A 18 gauge XTW introducer needle. A transvalvular insertion tube, which can be used to open the hemostasis valve during insertion of delicate leads or catheters, may also be packaged with the introducer kit. A Pacing Lead Stabilizer (PLS) that can be used to facilitate the removal of the introducer sheath, may also be packaged with the introducer kit.
Intended Use:	The SafeSheath MSP™ Introducer Sheath Kit with Integral Hemostasis Valve is for introduction of pacing leads or catheters during pacing lead or defibrillatory catheter placement procedures.

C. Comparison of Required Technological Characteristics

All technological characteristics of the SafeSheath MSP™ Introducer Sheath Kit with Integral Hemostasis Valve are substantially equivalent to the predicate device (K934901) including product design, packaging, sterilization, and labeling.

D. Substantial Equivalence

Thomas Medical Products considers the SafeSheath MSP™ Introducer Sheath Kit with Integral Hemostasis Valve to be substantially equivalent to the following legally marketed predicate devices: Tearaway Sheath Introducer Set with Integral Hemostasis Valve (K934901).

E. Qualification Testing

Thomas Medical Products qualification testing of the SafeSheath MSP™ Introducer Sheath Kit with Integral Hemostasis included dimensional, visual, leak testing, Valve Body to Sidearm pull test, PVC tubing to Stopcock pull test and PVC Tubing to Valve Housing Peel test. All samples passed the protocol qualification testing requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2001

Mr. Tim Stoudt
Manager, Quality Engineering
Thomas Medical Products, Inc.
65 Great Valley Parkway
Malvern, PA 19355

Re: K003731
Trade Name: SafeSheath MSP™ Introducer Sheath Kit
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: February 20, 2001
Received: February 21, 2001

Dear Mr. Stoudt:

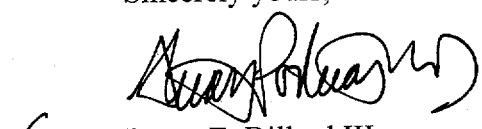
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K003731**

Device Name: **SafeSheath MSP™ Introducer Sheath Kit**

Indications For Use:

For the introduction of various types of pacing or defibrillator leads and catheters.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

4-9-1

Division of Cardiovascular & Respirat...
510(k) Number K003731